

PATENT COOPERATION TREATY



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 14 MAR 2005

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Applicant's or agent's file reference 21719 WO-HIL		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/13530	International filing date (day/month/year) 02.12.2003	Priority date (day/month/year) 06.12.2002	
International Patent Classification (IPC) or both national classification and IPC C12Q1/68			
Applicant ROCHE DIAGNOSTICS GMBH et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 09.06.2004		Date of completion of this report 16.03.2005	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer van Klompenburg, W Telephone No. +31 70 340-2243 	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/13530

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-33 as originally filed

Claims, Numbers

1-9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☒ furnished subsequently to this Authority in written form.
 - ☒ furnished subsequently to this Authority in computer readable form.
 - ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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EXAMINATION REPORT**

International application No. **PCT/EP 03/13530**

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	2-7
	No: Claims	1,8,9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO 01/48237 A (HOEFT ANDREAS ;STUEBER FRANK (DE)) 5 July 2001 (2001-07-05)

D2: ESPY ET AL: "Diagnosis of Herpes Simplex Virus Infections in the Clinical Laboratory by LightCycler PCR" JOURNAL OF CLINICAL MICROBIOLOGY, WASHINGTON, DC, US, vol. 38, no. 2, February 2000 (2000-02), pages 795-799, XP002175791 ISSN: 0095-1137

1 Clarity (Art.6 PCT)

1.1 In the statement of the problem on page 6 of the present application, notably lines 9-13 and 20-25, an essential effect of the present application distinguishing it from the prior art, is said to be **the detection of pathogenic organisms and not of non-pathogenic organisms**. The IPEA expressed the opinion that the essential technical features leading to this effect are the sequences of the combinations of primers and probes used. Since independent claims 1,8,9 do not contain these features, they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

1.2 It is also noted that the subject matter of claim 1 differs from what is agreed to be the essential effect of the invention (see above). Claim 1 is a method for identification of a pathogenic organism from a predetermined group of pathogens comprising a two-step detection step. By simply following the steps of claim 1 the skilled person would not necessarily arrive at said essential effect. This again points to lacking features in the independent claims.

2 Lack of Inventive Step (Art. 33(3) PCT)

2.2 D1 describes (examples 1-10) methods for the identification of a pathogenic organism from a predetermined group of microorganisms. The methods comprises amplification with a primer pair, detection with multiple hybridization reagents and monitoring temperature dependence of hybridization. The above is also demonstrated in

figures 1-13. The figures also include alignments of useful regions as target for amplification and hybridization.

Step bba comprises the expression: "**being indicative for at least the genus**". This expression is not found to be clear nor limiting to e.g. genus levels and higher taxons, or to genus level and lower taxons. The two step procedure of D1 comprises hybridization with "group" specific probes, exemplified by gram positive or negative bacteria, followed by melting curve analysis to detect the species.

Thus it is concluded that the subject-matter of claim 1 is anticipated by D1. Compositions and kits suitable for use in the method of claim 1 are implicit to the methods described in D1 and therefore also claims 8 and 9 are not novel (Art. 33(2) PCT).

2.2 D2 describes (Materials and Methods, pages 795-797) the identification of a pathogenic organism (HSV1 or HSV2) from a group of pathogenic organisms (HSV). Although quite special, viruses are generally regarded as organisms. Searching the Roche lexicon (<http://ard01/rochelexikon5a/>) with the word "virus" for instance yields a comparison with **other** microorganisms, implying that viruses are indeed organisms.

The method of D2 uses PCR primers, labelled probes and melting curve analysis (Table 1, figure 4). Therefore, the subject-matter of claims 1, 8 and 9 also lacks novelty over D2 (Art. 33(2) PCT).

The independent claims do not speak of discrimination between pathogenic and non-pathogenic (in contrast to the description at page 6), it is immaterial for novelty of those claims that D2 is silent on this distinction.

3 Inventive Step (Art. 33(3) PCT)

3.1 Dependent claims 2-7 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, involve an inventive step with respect to the prior art named in the present proceedings. The reasons therefor are that the additional features of the said dependent claims are a combination of features obvious to the skilled person in consideration of documents D1, D2 or any other document from the search report, or they concern minor modifications which lie within the normal practice of the skilled person.